Business Risk Management Procedure

Fisher & Paykel Healthcare Corporation Limited

Introduction

In working to achieve our purpose of improving care and outcomes through inspired and world-leading healthcare solutions, at Fisher & Paykel Healthcare (FPH) we must take calculated risks to achieve our objectives. To do this effectively, it is all of our responsibility to understand and manage the risks faced across our entire organisation. Risks are inherent in our business activities and can relate to strategic threats, operational issues, compliance with laws and regulations, financial and reporting obligations.

This document provides an overview of our enterprise-wide approach to risk management (Business Risk Management Procedure) and illustrates examples of how this approach is implemented within the organisation.

The objective is to describe:

- The purpose of risk management
- How risk is categorised
- The consistent procedure used to identify potential events that may affect the organisation
- Governance and oversight of risk management.

Purpose

The purpose of designing, implementing and maintaining an effective, structured approach to business risk management is to help improve the quality of decisions the business makes in the pursuit of achieving our growth objectives of providing an expanding range of innovative medical devices that improve care and outcomes.

This risk management procedure should not replace the natural ability of people to manage risk but rather should enhance good practice so that the process is reliable, comprehensive and consistent.

Adopting this procedure will result in benefits to all stakeholders, internal and external. Through this approach to risk management, we can:

- Increase the likelihood of achieving our business objectives
- Enhance our competitive advantage
- Deal with market instability more effectively
- Enable us to better meet customers' expectations, contractual and regulatory requirements
- Enhance shareholder and customer confidence
- Have confidence that the right risks are being taken and that decisions across the extended business are intelligent and informed.

Defining Risk

We face a wide range of internal and external sources of uncertainty, both positive and negative, that may affect our ability to achieve our objectives. Risk – the effect of uncertainty on objectives – is viewed as beneficial or detrimental depending on how it affects our objectives.

At FPH, risk is viewed as the combination of the probability of an event and the impact of its consequences. In order to deliver value to our stakeholders, we must understand the types of risks faced by our organisation and address them appropriately.

At FPH, risk to our success can be grouped into five categories: (1) Strategic, (2) Operational, (3) Compliance, (4) Financial and Reporting and (5) Reputational. Some examples of each type of risk are included in the table below.

Risk Types	Risk Examples
Strategic	• Inability to continue to innovate • Reduction in business viability (changing technology, market access issues, healthcare reform) • Commercialisation and protection of intellectual property
Operational	• Disruption to product supply • Physical damage to key manufacturing centres • Loss of critical systems for a prolonged period of time • People and physical capacity requirements cannot keep up with growth
Compliance	• Product quality / safety issues including violation of FDA and other health authority regulations • Employee health and safety • Selling and promotion of our products • Protection of personal data • Local tax and other laws • Intellectual property infringement

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Risk Types	Risk Examples
Financial and Reporting	• Foreign exchange volatility • Reporting requirements • Performance does not meet market expectations or FPH guidance
Reputational	• Significant product quality issue • Product recall • Breach of anti-trust laws • Ethical labour concerns

Components of Business Risk Management

Our risk management procedure is derived from ISO 31000 Risk Management – Principles and Guidelines and is enhanced to focus on FPH's key strategic objectives. At FPH, our approach is broken into five stages detailed below and focuses on business risk excluding product risk, for which ISO 14971 Medical Devices Application of Risk Management is the standard we follow specific to medical device design and manufacturing.

While no risk management system can ever be foolproof, our goal is to make sure that material risks are appropriately identified and managed within acceptable levels.

Governance and Oversight

The Board is ultimately responsible for overseeing the effectiveness of risk management, and the adequacy of the internal controls and assurance which it believes should be monitored and managed on a continuing basis. FPH has in place a number of risk management functions and systems which are intended to identify and manage areas of material business risk. These include:

Select Risk Management Functions	Strategic Risk	Operational Risk	Compliance Risk	Financial & Reporting Risk	Reputational Risk
Quality & Regulatory	✓	✓	✓		✓
Information Technology	✓	✓	✓		✓
Financial management & reporting	✓		✓	✓	✓
Legal & Compliance	✓		✓		✓
Facilities & Environment	✓	✓		✓	✓
Health & Safety		✓	✓		✓
Human Resources	✓				✓
Supply Chain	✓	✓	✓		✓

These systems provide managers and employees with:

1. A systematic and uniform process, together with the necessary tools and resources, to enable them to assist in the identification, assessment, monitoring and management of material business risks within their sphere of responsibility.
2. Clear communication channels regarding the reporting of material business risk issues and, if necessary, the procedure for escalating the issues which arise, or which have the potential to arise.

The CEO and senior management have the primary responsibility to advise the Board and its Committees of any material business risk issues, and for taking steps to address or prevent the occurrence or reoccurrence of such issues.

The Audit and Risk Committee is responsible for:

1. Reviewing whether FPH's risk management processes (excluding any risks related to FPH's quality, safety and regulatory functions) are capable of providing reliable information to the Board on the status of major risks that could impact on the achievement of FPH's objectives.
2. Reviewing FPH's operational and strategic risk assessments and determining whether the material business risks are being managed effectively.
3. Reviewing this document in conjunction with the risk management function every three years, or sooner where considered necessary.
4. Periodic review of the risk management system.

5. Reviewing and monitoring reporting to shareholders and other external stakeholders regarding sustainability, corporate and social responsibility, and environmental activities.

The Quality, Safety and Regulatory Committee is responsible for:

1. Reviewing FPH's quality, health and safety and regulatory risk management procedure to ensure that effective mechanisms and internal controls are in place to identify and manage areas of material risk and maintain compliance with applicable regulations.
2. Reviewing and monitoring FPH's quality objectives to assess the suitability and effectiveness of FPH's Quality Management System.
3. Reviewing and monitoring FPH's compliance with applicable regulations regarding the manufacture and distribution of medical devices.
4. Reviewing and monitoring reporting to shareholders and other external stakeholders regarding health and safety.

Approved by the Audit and Risk Committee on 27 September 2024.